

Appl. No. 10/706,103
Docket No. 9118M2
Amdt. dated April 19, 2010
Reply to Office Action mailed on January 27, 2010
Customer No. 27752

REMARKS

Claim Status

Claims 1-4 and 8-17 are pending in the present application. Claims 5-7 have been previously canceled without prejudice.

Claim 13, 14, and 16 have been amended to clarify the substance of the claims and to remove dependencies. It is believed these changes do not involve any introduction of new matter. Consequently, entry of these changes is believed to be in order and is respectfully requested.

Rejection Under 35 USC §103(a) over Kleinberg (US 6,436,370) in view of Coll-Palagos (US 4,309,409)

The Office Action rejects claims 1-4 and 8-17 over Kleinberg in view of Coll-Palagos. Applicants respectfully traverse.

To establish a *prima facie* case of obviousness under §103, the Examiner has the burden of showing, by reasoning or evidence, that: 1) there is some suggestion or motivation, either in the references themselves or in the knowledge available in the art, to modify that reference's teachings; 2) there is a reasonable expectation on the part of one of ordinary skill in the art that the modification or combination has a reasonable expectation of success; and 3) the prior art references (or references when combined) teach or suggest all the claim limitations. MPEP §2145. Applicants submit that the burden of a *prima facie* case of obviousness has not been met due to a failure of the prior art references teach or suggest all the claim limitations.

As understood, Kleinberg discloses an oral composition comprising a guanidinium alkaline salt and a calcium salt to treat dental hypersensitivity by plugging dental tubules. Kleinberg discloses "a conventional abrasive, such as resins, silica, and insoluble alkali metal nietaphosphates in a standard amount of about 20% to about 60% by weight." (Col. 6, lines 44-46).

Applicants fail to see the relevance of Kleinberg to the present invention. Kleinberg does not disclose any of the retentive agents in Applicant's claims. Applicants respectfully argue that abrasives are not the same as retentive agents. Applicants note that the present invention's specification provides disclosure of abrasives, such as resins and silicas, as an optional ingredient, but that such abrasives are distinct from the claimed retentive agents and, in fact, none of the abrasives are claimed in the present invention. (Specification, page 25, lines 20-28).

Furthermore, Kleinberg discloses nothing that would act as the claimed retentive agents do. The compositions of Kleinberg deposit material on a microscopic level. Dentinal tubules have a diameter of 2.5 microns near the pulp, 1.2 microns in the middle of the dentin, and 0.9 microns at the dentino-enamel junction. Their density is 59,000 to 76,000 per square millimeter near the pulp, whereas the density is only half as much near the enamel. (www.absoluteastronomy.com/topics/Dentin). In other words, particles that are plugging tubules must be at most 2.5 microns, which is a completely different scale than the composition of the present invention, which remains visible on several molars for 5 to 60 minutes after chewing, toothbrushing, and rinsing.

Coll-Palagos, while offering disclosure of one retentive agent, zinc oxide, of the present invention, fails to teach or suggest all the claim limitations of the present invention and, in fact, teaches away from several. For example, Coll-Palagos fails to teach or suggest a chewable solid unit dosage form. Coll-Palagos is quite clear that its composition is a creamy toothpaste that will be in a tube. The entire purpose for the invention in Coll-Palagos is to prevent corrosion of the inside of an unlined aluminum tube. (col 1, lines 20-51). Coll-Palagos clearly states, "In the dental cream formulation, liquids and solids are proportioned to form a creamy mass of desired consistency. In accordance with this invention, the creamy mass is packaged in a collapsible unlined aluminum tube." (col. 3, lines 4-8). In addition, all examples discuss placing the formulation in unlined aluminum tubes to test for corrosion.

Additionally, Coll-Palagos discloses that its final paste formulation, not just the anti-corrosion formulation itself, contains from about 0.05% to about 2.0% zinc oxide. (see col. 2, lines 11-14 as opposed to col. 1, line 67 to col. 2, line 1). This is far below the present invention's claimed amount of retentive agents, such as zinc oxide, from 30% to

Appl. No. 10/706,103
Docket No. 9118M2
Amdt. dated April 19, 2010
Reply to Office Action mailed on January 27, 2010
Customer No. 27752

65%. All the Coll-Palagos toothpaste formulation examples show zinc oxide levels at 1%.

As another example of Coll-Palagos teaching away from the present invention, Coll-Palagos specifically discusses that its formulations will have a pH from about 5.5 to about 6.8, again, to prevent corrosion of the unlined aluminum tubes. Claim 13 of the present invention specifically claims a method of buffering the oral cavity saliva or environment to a pH of 7 to 12. Other claims are for compositions comprising a buffer, which, as explained and supported in the specification, buffers the saliva or the environment on or at the tooth surfaces to a pH of from about 7 to about 12. (page 12, lines 13-22).

Applicants respectfully assert that a combination of Kleinberg and Coll-Palagos fails to teach or suggest all the claim limitations. One of ordinary skill in the art would not have been motivated by Coll-Palagos to add zinc oxide to a chewing gum version of Kleinberg, which has no similarity to the present invention's compositions or purpose. Coll-Palagos teaches a low pH and creamy formulation to avoid corrosion of aluminum tubes, so one would not be motivated by this to modify to a chewable solid unit dosage form. Furthermore, Coll-Palagos teaches that its final paste formulation, not just the anti-corrosion formulation itself, contains from about 0.05% to about 2.0% zinc oxide, far below the present invention's claimed amount of retentive agents, such as zinc oxide, from 30% to 65%. Applicants respectfully contend there is no motivation or suggestion in either reference to greatly increase the amount of zinc oxide in a toothpaste.

Therefore, a *prima facie* case of obviousness has not been established, and Applicants respectfully request that the rejection be withdrawn.

Rejection Under 35 USC §103(a) Over Lawlor in view of Fine (US 4,374,822) et. al.

Applicants note that the current Office Action specifically withdraws all the previous objections and rejections of the August 6, 2009 Office Action except for the rejection of claims 1-4 and 8-17 under 35 USC §103(a) as being unpatentable over Lawlor (US 6,706,256) in view of Fine, et al. (US 4,374,822) as evident by Grossman et

Appl. No. 10/706,103
Docket No. 9118M2
Amdt. dated April 19, 2010
Reply to Office Action mailed on January 27, 2010
Customer No. 27752

al. J. Dent. Res. 16(5), 409-416, 1937. Therefore, Applicants continue to traverse and respectfully argue that the cited references do not establish a *prima facie* case of obviousness.

Lawlor, as discussed in previous responses, does not disclose any of the claimed retentive agents at the levels used in the present invention. The Office Action (of Aug. 6, 2009) confirms this by noting that Lawlor fails to teach the percentage of the retentive particulate as 35-65% (bottom of page 12), and continues that Fine is introduced to teach specific claimed retentive particulate agents. Fine does not disclose any of the particulate retentive agents of the present claims. Therefore, because the prior art references and the combination of the prior art references do not teach or suggest all the claim limitations, Applicants contend that the burden of establishing a *prima facie* case of obviousness has not been met. Applicants respectfully request that the rejection be withdrawn.

Conclusion

This response represents an earnest effort to place the present application in proper form and to distinguish the invention as claimed from the applied references. In view of the foregoing, entry of the amendments presented herein, reconsideration of this application, and allowance of the pending claims are respectfully requested.

Respectfully submitted,

THE PROCTER & GAMBLE COMPANY

By /Kathleen Y. Carter/
Kathleen Y. Carter
Registration No. 60,583
(513) 983-2114

Date: April 19, 2010
Customer No. 27752